

THROMBECTOMY CATHETER

FIELD OF THE INVENTION

[0001] The invention relates to a thrombectomy or vascular aspiration catheter having modifications that significantly facilitate the performance of a thrombectomy within a patient's vessel. The invention further relates to procedures for performing a thrombectomy using improved catheter designs.

BACKGROUND OF THE INVENTION

[0002] An embolus can be any particle comprising a foreign and/or native material, which enters the vascular system or other vessel of the body with potential to cause occlusion of blood flow. Emboli can be formed from aggregates of fibrin, blood cells or fragments thereof, collagen, cholesterol, plaque, fat, calcified plaque, bubbles, arterial tissue, and/or other miscellaneous fragments or combinations thereof. Emboli can lodge in the narrowing regions of medium or small sized blood vessels that feed the major organs. Loss of blood flow to surrounding tissue causes localized cell death or infarction. Cerebral infarcts can cause stroke leading to confusion, disturbance of speech, paralysis, visual disturbances, balance disturbances and even death. In the heart, emboli can cause myocardial infarcts, i.e. heart attacks. Myocardial infarction refers to the death of a section of myocardium or heart muscle. Myocardial infarction can result from at least partial blockage of the coronary artery or its branches. Blockage of capillaries associated with the coronary arteries can result in corresponding microinfarctions/microinfarcts. The resulting impairment may be short term or permanent.

[0003] In some contexts, thrombus has been used to refer specifically to clots generally comprising fibrin and/or platelets. However, as used herein with respect to removal from a vessel, thrombus is used broadly to refer to any debris within a vessel that restricts or potentially restricts flow. Thus, thrombus is used interchangeably with debris and with emboli. Thrombus can result in undesirable restriction of flow within the vessel. In addition, release of thrombus from a particular location can result in a more serious blockage of flow downstream from the initial release location. Foreign material in the stream of flow can cause turbulence or reduced flow. Such flow conditions have been shown to increase rates of infection. Thrombus not only restricts flow, but also increases the risk of infection.

[0004] Disease states including, for example, arteriosclerosis and deep vein thrombosis, aging and even pregnancy can cause build up of plaque and fibrin on vessel walls. Anything that loosens or breaks up this plaque can generate emboli/thrombus. The clinical ramifications of emboli are staggering. Emboli generated from arteriosclerosis of the carotid artery alone cause 25% of the 500,000 strokes that occur yearly in the United States (2002 American Heart Association And Stroke annual statistics).

[0005] Ironically, percutaneous and surgical interventions used to remove or bypass the plaque of arteriosclerosis (e.g., balloon dilatation angioplasty, endarterectomy, bypass grafting and stenting) can themselves disrupt plaque. One of the most common cardiovascular interventions is coronary artery bypass grafting (CABG). Historically, 10-20% of all percutaneous coronary interventions in bypass grafts gener-

ate emboli large enough to cause myocardial infarcts. This is particularly true when the graft used is of saphenous vein origin. Other procedures also have the potential to generate emboli. In fact, doppler ultrasound shows evidence of microembolization in almost all cardiac and carotid intervention cases. Of the over 1.8 million intervention procedures performed annually, greater than 10% result in neurocognitive disturbance and/or ischemic events. These impairments are frequently short term, but can be permanent.

[0006] Percutaneous interventional procedures and surgical procedures for the treatment of renal artery stenosis can also generate emboli. There is clinical evidence to suggest that 36% of those treated suffer arteriolar nephrosclerosis caused by atheroemboli. Five-year survival of patients with atheroembolic events is significantly worse than of patients without atheroemboli (54% vs. 85% respectively) [Krishnamurthi et al. J Urol. 1999, 161:1093-6].

[0007] Pulmonary embolism to the pulmonary arteries from deep veins of the legs is another major clinical problem, often with a large embolic load. Patients with the potential for pulmonary embolism may benefit from thrombus removal.

SUMMARY OF THE INVENTION

[0008] In a first aspect, the invention pertains to a thrombectomy catheter comprising a suction device, a proximal portion fluidly connected to the suction device, a tubular shaft attached at its proximal end to the proximal portion, and a tip portion at the distal end of the tubular shaft. A continuous suction lumen extends from the proximal portion to the tip portion. Furthermore, the tip portion comprises a suction port in fluid communication with the suction lumen. In some embodiments, the tip portion has a first configuration and a second configuration that is curved relative to the first configuration.

[0009] In a further aspect, the invention pertains to a thrombectomy catheter comprising a suction device, a proximal portion fluidly connected to the suction device, a tubular shaft attached at its proximal end to the proximal portion, and a tip portion at the distal end of the tubular shaft. A continuous suction lumen extends from the proximal portion to the tip portion, and the tip portion comprises a suction port in fluid communication with the suction lumen. In some embodiments, the tip portion has a curve to present a displacement from the tip's natural outer diameter of at least about 2 or 3 mm.

[0010] In another aspect, the invention pertains to a thrombectomy catheter comprising a suction device, a proximal portion fluidly connected to the suction device, a tubular shaft attached at its proximal end to the proximal portion, and a tip portion at the distal end of the tubular shaft. A continuous suction lumen extends from the proximal portion to the tip portion, and the tip portion comprises a suction port in fluid communication with the suction lumen. In some embodiments, the tip portion having a curved structure that provides at least three curved segments.

[0011] In additional aspects, the invention pertains to a method for removing thrombus from a vessel of a patient. The method comprises aspirating fluid and particulate matter from the vessel through a suction port in a thrombectomy